

**REMARKS**

This amendment responds to the Office Action dated November 6, 2006. Claims 1-6 and 44-51 are in the application. Claims 1 and 44 are in independent form. Claims 9, 10, 13, 15-17, 19-23, 26-28, 30 are cancelled by this amendment.

Applicants' attorney thanks the Examiner for the courtesies rendered during the March 21, 2007 telephonic interview. The remarks below incorporate the subject matter discussed during the interview.

Reconsideration is respectfully requested in light of the following remarks.

**35 USC § 103**

The claims stand rejected under 35 USC § 103 for obviousness over U.S. Pat. No. 6,611,806 to Harvey ("Harvey") in view of U.S. Pat. No. 5,771,657 to Lasher ("Lasher") and others. Applicants respond as follows.

Harvey is directed to a computer system for tracking the lot numbers of pharmaceuticals that are administered to patients. The system includes a plurality of remote systems, each typically at a different hospital. Each remote system associates the lot numbers of pharmaceuticals that are administered to patients. As described by Harvey, there is great value in being able to quickly and efficiently track the patients to whom pharmaceuticals, such as blood derivatives, have been administered. One example is product recall. Occasionally, a pharmaceutical will be recalled by its manufacturer or by the FDA. The ability to track pharmaceuticals to patients is also of great importance to research. Fast and efficient tracking can facilitate the evaluation of drug effectiveness.

Lasher is directed to an automated prescription dispensing and packing system, empty prescription bottles are labeled and loaded in assigned locations in carriers. Pills are automatically dispensed into the prescription bottles in the carriers. Ranks of carriers containing filled prescription bottles are assembled at stations where the bottles are unloaded and packed into shipping containers with literature printed by the system. Multiple bottles of an order are automatically packed in the same shipping container.

Amended claim 1 recites a method for tracking physical location of prescription

orders through a pharmacy in which prescription orders being moved between the plurality of spaced apart locations by one or more pharmacy workers by hand. The reference to moving prescription orders by hand is a substitution for and clarification of the prior reference of the prescription orders being moved manually.

The pharmacy has a storage area with an array of compartments for storing filled prescription orders therein, the method includes the steps of operably securing a machine-readable tag to a prescription order upstream of the storage area, and moving the prescription order by hand to one of the compartments in the array of compartments as a filled prescription order, each compartment having a corresponding compartment tag reader that is in communication with the computer system and is operable to read the unique identifier of the tag on the filled prescription order regardless of the orientation of the tag.

The Examiner previously stated that Harvey discloses a method of tracking prescription orders through a pharmacy and includes the step of operably securing remote machine-readable tag to the prescription order (citing Harvey, col 4, lines 16-56) and associating the tag with customer information. The Examiner notes that Harvey does not disclose manually moving the prescription order to one compartment in of an array of compartments, each of which has a compartment tag reader, and automatically recording the compartment where the filled prescription is located. The Examiner cites Lasher as disclosing these features and concludes that it would have been obvious to combine the features of Lasher with the system of Harvey. Applicants respond as follows.

Harvey is directed to a system for tracking the lot numbers of prescriptions that have been delivered to customers, as described by Harvey at col. 4, lines 16-27:

A key feature of the present invention is to record an association between each prescription issued by the physician which is to be tracked and the lot number or numbers of the pharmaceuticals that are actually administered to the patient in fulfillment of the prescription. Although referring to the information that identifies a particular pharmaceutical as a lot number, it is to be understood that the phrase "lot number" is intended to connote any type of information that is used to identify the pharmaceutical, whether it is called a "lot number" or not. This includes information that identifies a particular batch or set of products that is administered to a patient, or any other type of organizational arrangement.

The tracking of lot numbers described by Harvey merely adds an additional information field to records of dispensed prescriptions. The additional information field is used not

to improve the accuracy of dispensing prescriptions, but rather to identify after delivery of the prescription which manufacturing batch the prescription came from for purposes of recall or analysis. Nothing in the Harvey system provides any teaching or suggestion of tracking the physical location of individual prescription orders within a pharmacy to provide increased accuracy in the dispensing of prescriptions.

In response to applicants' prior argument that neither Harvey nor Lasher teaches the tracking of the physical locations of prescription orders within a pharmacy, the Examiner cites only Harvey as teaching the tracking of the physical locations of prescription orders within a pharmacy, citing Fig. 2, and col. 5, lines 18-65. Applicants reproduce below a copy of Fig. 2 of Harvey:

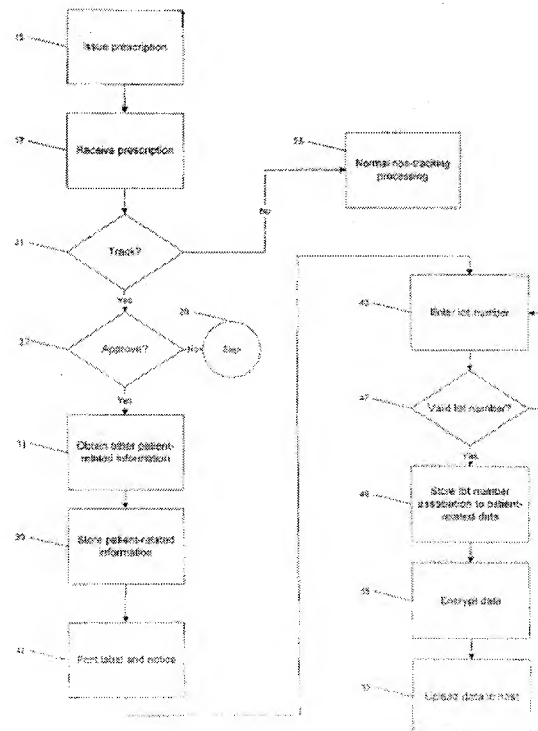


Figure 2

Applicants notes that Fig. 2 illustrates a method of tracking lot numbers associated with prescriptions, but makes no mention or suggestion of tracking physical location of prescriptions within a pharmacy. Indeed, Harvey makes no teaching or suggestion of any structure or mechanism for detecting the physical locations of prescriptions within a pharmacy. Likewise, the passage of Harvey cited by the Examiner (col. 5, lines 18-65, reproduced below) makes no mention of determining the physical location of a prescription order within a pharmacy.

In order to implement this embodiment of the present invention, the data monitoring program 23 is simply added and runs in the background. While running in the background, the data monitoring program 23 monitors the data that is entered and managed by the data entry program 19 for the entry of a prescription that needs to be tracked, e.g., a prescription that has been listed in a table of prescriptions to be tracked. In other words, the data monitoring program 23 operates in the background and monitors the prescriptions that are being processed by the station 11 in search of a prescription that is to be tracked.

As a result, the monitoring function is transparent to the user. In one embodiment, the running of the background data monitoring program 23 is inconspicuously indicated to the user of the station 11 by a small icon at the bottom of the desktop of the station 11.

The invention embraces all techniques for performing this background-monitoring function, including the many that are well-established and understood, including screen scraping, direct database calls, and the monitoring of API calls.

If the prescribed pharmaceutical is not listed in the table of pharmaceuticals to be tracked, the normal processing of such pharmaceuticals on remote entry station 11 would then proceed, as reflected by a Normal Non-Tracking Processing block 25 in FIG. 2. If the prescribed pharmaceutical is on the list of pharmaceuticals to be tracked, on the other hand, the next step of this embodiment of the invention is to proceed to the Approve box 27 in FIG. 2.

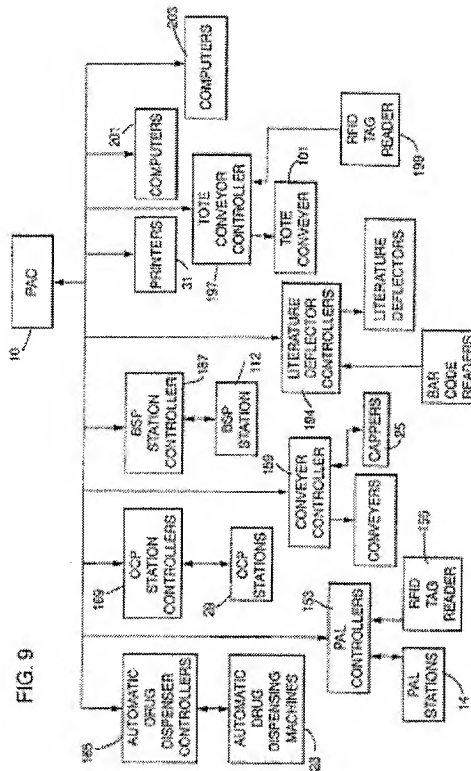
The Approve box 27 is directed to the existing process that the pharmacist follows to approve the prescription before the prescribed pharmaceutical is dispensed. As is well known, approval of a prescription by a pharmacist is a well-respected and widely implemented patient safeguard in the prescription process.

In one embodiment of the present invention, the pharmacist signifies his approval or disapproval by making appropriate entries under the control of the data entry program 19 in the remote station 11, just like he did prior to upgrading to implement the present invention.

In one embodiment of the present invention, status of this approval is also monitored by the data monitoring program 23. If approval is not given, tracking of the prescribed pharmaceutical is halted, as reflected in the Stop block 29 in FIG. 2. If approval is given, on the other hand, the invention proceeds to an Obtain Other Patient Related Information block 31, as also reflected in FIG. 2.

Harvey describes the "tracking" of prescriptions to determine what pharmaceuticals are delivered to patients, not to determine where prescription orders are physically located within a pharmacy. As with Fig. 2 cited by the Examiner, the passage set forth above makes no mention or suggestion of any mechanism or structure capable of detecting the physical location of a prescription order. Applicants submit, therefore, that the Harvey reference specifically relied upon by the Examiner to teach the tracking of the physical location of a prescription order within a pharmacy provides no mention of such tracking and no mention of any structure or mechanism capable of providing such tracking. Applicants submit that the rejection is improper and should be withdrawn.

In response to applicants' prior argument that Harvey does not teach machine readable tags being secured to prescription orders, the Examiner cites Lasher, Fig. 9, col. 13, lines 50-67, col. 14, line 14, and col. 15, lines 51-67. Applicants reproduce below a copy of Fig. 9 of Lasher.



As described at col. 3, lines 27-28, Fig. 9 illustrates “the architecture of the computer system used in the system of the present invention.” Fig. 9 does not show prescription orders or machine readable tags that are secured to prescription orders. Likewise, the passage of Lasher cited by the Examiner (reproduced below) make no mention of machine readable tags that are secured to prescription orders.

As shown in FIG. 9, PAC 10 controls the components of the system through a distributed logic system. PAC 10 receives the prescriptions from the host computer and stores the prescriptions in the order file. PAC 10 controls the PAL stations 14 via controllers 153. PAC 10 makes a batch file for each carrier containing the prescription information for each prescription to be loaded into the corresponding carrier and the exact locations in the carrier where the prescription bottles of the prescriptions are to be placed. These batch files are transmitted to the controller 153 which controls label printers of the PAL stations 14 to print the bottle prescription labels, label the bottles, and control the PAL stations to load the labeled bottles in the scheduled locations in a carrier. Transducers 155 read the carrier identification from the RFID tag when a carrier has been loaded at a PAL station and the loaded carrier is dispatched to an automatic drug dispensing machine and controllers 153 transmit the carrier identification to PAC 10. PAC 10 stores the carrier identifications of the carriers in association with the scheduled locations for the prescription bottles loaded in these carriers and with the corresponding orders so that for each order, PAC can retrieve the carrier identifications and the scheduled locations in the carriers of the prescription bottles for the order.

The conveyer system is controlled by PAC 10 via carrier conveyer controller 159. When the PAL stations have completed loading of the orders in the batch file into a rank of carriers, PAC 10 issues a move instruction to the conveyer controller 159 to cause the conveyers 45 to transport the rank of carriers now filled with labeled empty prescription bottles to the automatic drug dispensing machines 23. The controller 159 also controls the cappers 25.  
(Col. 13, line 50 - col. 14, line 14.)

PAC 10 also interfaces with computers 201 at the quality assurance area 109 and with computers 203 at the package quality assurance area 96. The computers 201 and 203 provide information to pharmacists or technicians about the orders and prescriptions in the packages and prescription

bottles received at these quality assurance areas.

The above-described system automatically dispenses tablets and capsules into prescription bottles, assembles the prescription bottles for a common order into shipping containers, prints literature packs for each order and automatically inserts the literature packs into the shipping containers and prints the mailing labels on the shipping containers so that upon completion of the automatically operated system the order is ready to be mailed.

The above automatic system is accomplished with a very high throughput of orders and, at the same time, provides for checks and balances to make sure that the system is operating properly and provides for automatically diverting orders and bottles for manual inspection for problems in the automatic system that have been detected.  
col. 15, line 51- col. 16, line 3.)

The specification passages of Lasher cited by the Examiner do not teach or suggest machine readable tags being secured to prescription orders. Rather, Lasher is directed to applying a machine readable tag to each carrier within which 24 separate prescription are carried:

Transducers 155 read the carrier identification from the RFID tag when a carrier has been loaded at a PAL station and the loaded carrier is dispatched to an automatic drug dispensing machine and controllers 153 transmit the carrier identification to PAC 10. PAC 10 stores the carrier identifications of the carriers in association with the scheduled locations for the prescription bottles loaded in these carriers

The application of tags to carriers of prescription bottles, rather than to prescription orders as recited in the claims, is further clarified in the description of Lasher Figs. 4A and 4B:

As shown in FIGS. 4a and 4b, a bottle carrier has 24 wells 44 to receive bottles which are arranged in a 4.times.6 array. The leading row which consists of four wells are sized to accommodate the large sized bottles and the remaining five rows are sized to receive the small bottles. This breakdown is a close approximation to the anticipated requirements for large and small bottles. The bottles all have the same diameter, as do the wells, but the wells in the first four rows are deeper to accommodate the larger bottles which have a greater axial dimension. The well bottoms in the carriers are positioned so that the tops of the bottles loaded in the carriers are all at the same level.

The bottle carrier is also provided with an RFID tag 46 which uniquely identifies the carrier. The carrier identification can be read out from the RFID tag by radio frequency transducers. The RFID tags and transducers are available from Data Logic Company. After a carrier is loaded at a PAL station, the RFID tag on the carrier is read and stored by PAC 10 in the order file associated with the prescription orders of bottles loaded on the carrier.

Each bottle becomes unique when the label is applied to the bottle, and it must be placed at a predetermined scheduled position within the bottle carrier by a PAL station 14. It is critical that no deviation occur between the logical position of the bottle determined by PAC and the physical location of the bottle on the carrier.

Lasher describes applying machine readable tags to carrier trays in which a machine carries 24 separate prescription bottles. Lasher does not apply a separate tag to each prescription order, as recited in amended claim 1. Moreover, Lasher is specifically directed to an automated machine for handling prescriptions and does not teach or suggest prescription orders being moved by hand, as recited in the claim.

The use of separate tags for separate prescription orders, as recited in claim 1,

provides physical tracking of individual prescription orders in a pharmacy where the prescription orders are moved by hand, thereby providing reliable location tracking of each individual prescription order. In contrast, Lasher employs only one tag per 24 prescription bottles because Lasher is directed to a fully automated handling system. Lasher teaches away from moving prescription bottles by hand and rather is directed to a fully-automated system that is directed to mail-order pharmaceutical suppliers:

The use of mail service to fill prescriptions has been highly successful in lowering the costs of providing drugs to consumers. The filling of prescriptions and mailing the filled prescriptions to consumers is labor intensive and a pharmacy can significantly reduce its costs, improve quality, and reduce turn around time by automating the prescription filling and assembling procedures. (Lasher, col. 1, lines 11-17.)

Such large-scale automated machines are too bulky and expensive for most retail pharmacies and are unrelated to the operation of such pharmacies. Applicants submit, therefore, that the Lasher reference specifically relied upon by the Examiner to teach operably securing machine readable tags to prescription orders provides no mention of applying a separate tag to each order to accommodate that moving or prescription orders by hand, as recited in claim 1. Applicants submit that the rejection is improper and should be withdrawn.

Moreover, Lasher is directed to a fully automated prescription dispensing and packing system. Such fully automated systems are incompatible with many pharmacy operations, as described in the application at page 4, lines 1-15:

Similarly, some pharmacy vendors have attempted to automate the prescription filling aspect of a pharmacy by incorporating an automatic assembly line process for filling prescription orders. In particular, an operator enters a prescription order into a computer system, which causes a conveyor-type system to deliver an empty vial to an automated drug dispenser. The filled vial is then automatically matched with a label and presented to a pharmacist for final review and approval. While these types of devices facilitate the quick and efficient filling of prescription orders, they are expensive for use in a retail pharmacy environment, and they occupy a large amount of limited space within the pharmacy. Moreover, they still require pharmacy workers to perform manual tasks such as verifying insurance and renewability of the prescription, and processing the various forms of prescription orders before and after they are entered into the automated system. Accordingly, they do not permit the easy tracking of prescription orders as they travel within the automated pharmacy environment.

Independent claims 1 and 44 each recites moving prescription orders by hand to one of the compartments in an array of compartments as a filled prescription order.

The Examiner has previously cited Lasher as disclosing the “manual moving” recited in the claim. Amended claims 1 and 44 clarify that the recited movement of prescription orders is performed by hand and so is distinct from the fully automated prescription-filling machine of Lasher. The fully automated system of Lasher is explicitly directed to machine handling of sets of 24 prescription bottles. The fully automated system of Lasher has no basis for determining the location of individually handled prescription orders. Applicants submit, therefore, that the rejection is improper and should be withdrawn.

Applicants submit that independent claim 44 is patentably distinct from the cited references for the reasons set forth above in reference to claim 1. More specifically, claim 44 recites operably securing a machine-readable tag to the prescription order, the machine-readable tag having a unique tag identifier, placing the filled prescription order and the machine-readable tag by hand into a pharmacy worker selected storage area, and retrieving the filled prescription order by hand from the identified pharmacy worker selected storage area. Applicants submit that the cited references do not teach or suggest these claimed features and that the rejection of claim 44 should be withdrawn.

More specifically, Harvey provides no teaching or suggestion of tracking the physical location of a prescription order within a pharmacy. Harvey merely “tracks” the lots numbers of pharmaceuticals that have been distributed to patients. In addition, Lasher provides no teaching or suggestion of applying machine readable tags to prescription orders. Instead, Lasher is directed to applying tags to prescription bottle carriers, which carry 24 separate prescription bottles, in a fully automated system.

In addition, the fully automated system of Lasher is directed specifically to avoiding moving prescription orders by hand, as recited in claim 44, because the fully automated system of Lasher is directed to a mail order prescription service rather than to a retail pharmacy environment. The fully automated system of Lasher avoids worker handling of individual prescription orders, such as by placing filled prescription order by hand into pharmacy worker selected storage areas and retrieving the filled prescription order by hand therefrom. Moreover, the cost, complexity and size of the fully automated system of Lasher is incompatible with the pharmacy environment recited in the claim. Applicants submit that the cited references do not teach or suggest these



claimed features and that the rejection of claim 44 should be withdrawn.

Applicants submit that independent claims 1 and 44 are patentably distinct from the cited references for the reasons set forth above and that the rejections should be withdrawn. The dependent claims should be allowed as depending from patentably distinct base claims. In addition various ones of the dependent claims are further patentably distinct for the following reasons.

Claim 2 further recites displaying on a computer system the compartment in which any selected prescription order is stored, as described in the application beginning at page 8, line 27, for example. Harvey describes absolutely no mechanism or structure for tracking physical location or prescription orders in a pharmacy. Lasher describes a fully automated system that has no mechanism for displaying prescription locations. The fully automated nature of the Lasher system eliminates the need to locate prescription orders at arbitrary points in the workflow stream, as is commonly necessary in a pharmacy environment with manual handling. The only mention in Lasher of displaying information is that "the scan of the bottle bar code will bring up a display on the pharmacist's terminal which includes all the information regarding the particular prescription." (Lasher, col. 12, lines 1-9.) Applicants submit, therefore, that claim 2 is patentably distinct and request that the rejection be withdrawn.

Claim 3 recites moving prescription orders by hand to a second location within the pharmacy upstream of the storage area, the second location having a second location tag reader in communication with the computer system. Lasher is directed to a fully automated system that makes no provision for movement of prescription orders by hand. As a result, Lasher provides no teaching or suggestion of detecting the locations of individual prescription orders, whether at a storage area or at a second location upstream of the storage area. Lasher is directed only to tracking a prescription bottle carrier with a fixed set or prescription bottles. Applicants submit, therefore, that claim 3 is patentably distinct and request that the rejection be withdrawn.

Claim 4 is directing to collecting timing information about the time each prescription order remains at the second location and compiling workflow information, and claim 5 is directed associating the workflow information with workers for evaluating them. Harvey describes absolutely no mechanism or structure for tracking physical

location or prescription orders in a pharmacy. Lasher describes a fully automated system that is intended to minimize worker handling. Such fully automated handling eliminates the need for tracking timing information for individual prescription orders at a selected location because the workflow is automatically fixed. In the absence of manual handling prescription orders there is no mechanism for individual orders to fall behind the normal workflow. As a result, the fully automated system of Lasher makes any mention of collecting timing information about the time each prescription order remains at the second location and compiling workflow information, or associating the workflow information with workers for evaluating them. Applicants submit, therefore, that claims 4 and 5 are patentably distinct and request that the rejection be withdrawn.

Claim 6 recites that the pharmacy is a retail pharmacy. Harvey describes absolutely no mechanism or structure for tracking physical location or prescription orders in a pharmacy. Lasher describes a fully automated system that is directed specifically to mail order pharmaceutical operations. (Lasher, col. 1, lines 10-13.) The fully automated system of Lasher is a substitute for and incompatible with the claimed manual handling of prescription orders in retail pharmacies. Applicants submit, therefore, that claim 6 is patentably distinct and request that the rejection be withdrawn.

Amended 48 claim recites detecting removal of the filled prescription order and its associated tag from the pharmacy worker selected storage area. Harvey describes absolutely no mechanism or structure for tracking physical location or prescription orders in a pharmacy. Lasher describes a fully automated system that provides no mechanism tracking individual prescription orders. The fully automated system of Lasher tracks carriers that each hold 24 prescription bottles. Lasher describes no mechanism or system for detecting removal of a bottle from one of the carriers. Applicants submit, therefore, that claim 48 is patentably distinct and request that the rejection be withdrawn.

Amended claim 49 recites monitoring with the computer system the time the filled prescription order and its associated tag remains within the pharmacy worker selected storage area and returning the filled prescription order to stock if the prescription order is not picked up within a predefined time limit. As described in the application at page 19, lines 15-19, such monitoring allows filled prescription orders be returned to stock if they are not picked-up within a set number of days. Harvey

describes absolutely no mechanism or structure for tracking physical location or prescription orders in a pharmacy. Lasher describes a fully automated system that is used in a mail order pharmaceutical system. There is no basis by which prescriptions would not be "picked up" in the mail order application of Lasher. Applicants submit, therefore, that the cited references do not teach or suggest the subject matter of claim 49 and request that the rejection be withdrawn.

Claims 50 and 51 are directed to two separate prescription orders occupying a common compartment in the storage area, and distinguishing the two prescription orders by means of their associated tags secured. Claim 51 is directed to automatic detection of a specific prescription order being removed from the common compartment.

Harvey describes absolutely no mechanism or structure for tracking physical location or prescription orders in a pharmacy. Lasher describes a fully automated system in which prescription bottles have distinct places in a bottle carrier. There is no mechanism for two prescription bottles in the automated system of Lasher to occupy a common compartment. Moreover, in the absence of any tags being applied to individual prescription orders, Lasher provides no teaching or suggestion of detecting removal of a specific prescription order from a common compartment. Applicants submit, therefore, that the cited references do not teach or suggest the subject matter of claims 50 and 51 and request that the rejection be withdrawn.

Moreover, applicants submit that there is no teaching or suggestion to combine the references as proposed by the Examiner. Harvey is directed to collecting lot or batch information about prescribed pharmaceuticals that have been distributed to customers. Harvey is not remotely directed to or concerned with the tracking of physical locations of prescription orders within a pharmacy. In contrast, Lasher is directed to a fully automated prescription system that has no moving of prescriptions in the absence of computer control. Applicants submit that any combination of Harvey and Lasher would result in a fully automated prescription system that also tracks lot numbers, not the physical tracking method of the present invention for prescriptions that includes worker selection of storage areas. Accordingly, applicants submit that claim 44 and its dependent claims 45-51 are patentably distinct from the cited references and request that the rejection be withdrawn.

Added claim 62 recites in an alternative format subject matter analogous to that of claim 1. Claims 63-65 recite subject matter analogous to that of claims 2, 3, and 48. Applicants submit that the added claims are allowable for the reasons set forth above in reference to claims 1-3 and 48.

### CONCLUSION

In view of the foregoing, applicants submit that all of the currently pending claims are in condition for allowance, and respectfully request that the case be passed to issuance. If the Examiner has any questions, he is invited to contact applicants' attorney at the below-listed telephone number.

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Respectfully submitted,

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